

REMARKS

This Amendment is in further response to the Examiner's Official Action mailed October 3, 2003. Claim 7 has been amended. Claims 1-22 are now pending.

I. Obviousness-Type Double Patenting Rejection over the '379 Patent

Claims 1-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of US Patent No: 6,492,379 (the '379 patent). The reason for the Examiner's rejection is merely because claims of both the instant application and the '379 patent recite a polymorphic form of 9-nitrocamptothecin (9NC).

Applicants disagree with the Examiner that the claimed invention is not patentably distinct from the '329 patent. Claim 1 of the Application specifies a polymorphic form of 9NC having the following distinct spectral characteristics: by differential scanning calorimetry, an endotherm at between 273.9 to 275.9°C, and an exotherm at between 279.3 and 281.3°C.

In contrast, the crystal form of 9NC disclosed in the '379 patent is in a different form having the following spectral characteristics as recited in claim 1 of the patent:

- 1) an endotherm at between 175.5 and 177.5°C and an exotherm at between 181.7 and 183.7°C, and
- 2) an IR spectrum with no absorption centered between 3625 cm⁻¹ and 3675 cm⁻¹.

As shown above, these two crystal forms of 9NC recited in the claim 1 of the instant application and the '379 patent have distinctly different endotherm/exotherm profiles and thus are non-obvious in view of each other.

However, to expedite the prosecution, Applicants submit herewith a terminal disclaimer over the '379 patent. Withdrawal of the rejection is therefore respectfully requested.

II. Obviousness-Type Double Patenting Rejection over the '830 Patent

Claims 1-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of US Patent No: 6,482,830 (the '830 patent). The reason for the Examiner's rejection is merely because claims of both the instant application and the '830 patent recite a polymorphic form of 9-nitrocamptothecin (9NC).

Applicants disagree with the Examiner that the claimed invention is not patentably distinct

from the '830 patent. As discussed above, claim 1 of the Application specifies a polymorphic form of 9NC having the following distinct spectral characteristics: by differential scanning calorimetry, an endotherm at between 273.9 to 275.9°C, and an exotherm at between 279.3 and 281.3°C.

In contrast, the crystal form of 9NC disclosed in the '830 patent is in a different form having the following spectral characteristics as recited in claim 1 of the patent: an endotherm at between 149.2 and 151.2°C, an exotherm at between 162.6 and 164.6°C, and an exotherm at between 272 and 274°C.

As shown above, these two crystal forms of 9NC recited in the claim 1 of the instant application and the '830 patent have distinctly different endotherm/exotherm profiles and thus are non-obvious in view of each other.

However, to expedite the prosecution, Applicants submit herewith a terminal disclaimer over the '830 patent. Withdrawal of the rejection is therefore respectfully requested.

III. Obviousness-Type Double Patenting Rejection over the '530 Application

Claims 1-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of co-pending Application No: 10/080,530 (the '530 application). The reason for the Examiner's rejection is merely because the instant application and the '530 application are claiming a common subject matter: a polymorphic form of 9NC.

Applicants disagree with the Examiner that the claimed invention is not patentably distinct from the '530 application. As discussed above, claim 1 of the instant application specifies a polymorphic form having following distinct spectral characteristics: an endotherm at between 273.9 to 275.9°C, and an exotherm at between 279.3 and 281.3°C.

In contrast, the crystal form of 9NC disclosed in the '530 applications is in a different form having the following spectral characteristics as recited in claim 1:

1) by differential scanning calorimetry, no observable endotherm and an exotherm at between 273.6 and 275.6°C; and

2) a solution NMR spectrum with multiplets at 1.7 and 3.7 ppm shifts.

As shown above, the claimed crystal form of 9NC of the instant application has an endotherm at between 273.9 to 275.9°C whereas the crystal form claimed in the '530 application does not have an observable endotherm, and the exotherm range does not overlap with that of the claimed crystal form of 9NC. These two crystal forms of 9NC are distinctly different from each other and non-obvious in view of each other.

However, to expedite the prosecution, Applicants submit herewith a terminal disclaimer over the '530 application. Withdrawal of the rejection is therefore respectfully requested.

CONCLUSION

In view of the above amendment and remarks, Applicants earnestly believe that they are entitled to a letters patent, and respectfully solicit the Examiner to expedite prosecution of this patent application to issuance. Should the Examiner have any questions, Examiner is encouraged to telephone the undersigned.

Respectfully submitted,

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